PLANNING GRANT FOR CLINICAL RESEARCH TRAINING IN MINORITY INSTITUTIONS

Release Date: September 26, 2000

RFA: AR-00-009

Office of Research on Minority Health
National Cancer Institute
National Center for Research Resources
National Center for Complementary and Alternative Medicine
National Eye Institute
National Institute on Aging
National Institute of Allergy and Infectious Diseases
National Institute of Arthritis and Musculoskeletal and Skin Diseases
National Institute of Dental and Craniofacial Research
National Institute of Diabetes and Digestive and Kidney Diseases
National Institute of Drug Abuse
National Institute of Nursing Research

Letter of Intent Receipt Date: October 23, 2000
Application Receipt Date: December 19, 2000

THIS RFA USES THE "MODULAR GRANT" AND "JUST-IN-TIME" CONCEPTS. IT INCLUDES DETAILED MODIFICATIONS TO STANDARD APPLICATION INSTRUCTIONS THAT MUST BE USED WHEN PREPARING APPLICATIONS IN RESPONSE TO THIS RFA/PA.

PURPOSE

The Office of Research on Minority Health (ORMH) joins the National Cancer Institute (NCI), National Center for Research Resources (NCRR), National Center for Complementary and Alternative Medicine (NCCAM), National Eye Institute (NEI), National Institute on Aging (NIA), National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAID), National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), National Institute of Dental and Craniofacial Research (NIDCR), National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institute of Drug Abuse (NIDA), and the National Institute of Nursing Research (NINR) to invite Minority Institutions with professional

schools in one or more of the health care disciplines to apply for a planning grant to develop a Master of Clinical Research or a Master of Public Health in a clinically relevant area.

This RFA is intended to stimulate the inclusion of high-quality, multidisciplinary didactic training as part of the career development of clinical investigators being trained in Minority institutions. The planning grant supports the initial assessment needed to begin development and/or improvement of core courses designed as in-depth instruction in the fundamental skills, methodology, theories, and conceptualizations necessary for the well-trained, independent, clinical investigator. While many NIH programs support research experiences for new clinicians, not all of these trainees have the opportunity to receive formal course work in the design of clinical research projects, hypothesis development, biostatistics, epidemiology, disease mechanisms, medical technology, human genetics, and the legal, ethical and regulatory issues related to clinical research. This award is intended to initiate the development of new didactic programs in clinical research at minority institutions that do not currently offer such programs or, in institutions with existing didactic programs in clinical research, to support and expand their programs or to improve the quality of instruction. The goal of this program is to improve the training of the clinical investigators, so that upon completion of their training, they can more effectively compete for research funding.

HEALTHY PEOPLE 2010

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This Request for Applications (RFA), PLANNING GRANT FOR CLINICAL RESEARCH TRAINING IN MINORITY INSTITUTIONS, is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at http://www.health.gov/healthypeople/.

ELIGIBILITY REQUIREMENTS

A. Minority Institution. The institution must be a domestic, non-Federal organization, such as medical, dental or nursing schools, from comparable institutions of higher education, or research institutions that have ongoing clinical research and/or clinical research training programs. The applicant institution must serve students from minority ethnic groups underrepresented in the biomedical sciences (e.g. African Americans, Hispanics, American Indians, Alaskan Natives, Native Hawaiians, and Pacific Islanders) comprising a majority (more than 50%) of the institution’s enrollment. It must have faculty and facilities for the proposed program and must

conduct ongoing clinical research. The institution must demonstrate the commitment and capability to develop a core curriculum leading to a Master of Clinical Research degree or a Master of Public Health in a clinically relevant area. An institution may submit only one application. Applicants are encouraged to develop consortia in a common geographic location to enhance the depth of their faculty and participant pool, or to improve the quality of the educational experience.

B. Potential Participants. The institution must document a cadre of doctorally qualified individuals for the proposed program. All potential participants must be U.S. citizens, non-citizen nationals or lawfully admitted permanent residents of the U.S. This program is intended to include participants who hold or have matriculated for the following degrees: M.D., D.D.S., D.M.D., D.O., D.C., O.D., N.D. (Doctor of Naturopathy), doctorally prepared nurses, Ph.D. with clinical responsibilities, or Pharm.D. Since clinical research is multidisciplinary, participants in this program should represent diverse academic backgrounds. Interactions during the early years of career development may serve to enhance the team approach necessary to meet the multidisciplinary challenges of clinical research. Ph.D.s who want to become involved in clinical research may also participate.

MECHANISM OF SUPPORT

Specific application instructions have been modified to reflect "MODULAR GRANT" and "JUST-IN-TIME" streamlining efforts being examined by the NIH. Complete and detailed instructions and information on Modular Grant/Just in Time applications can be found at http://grants.nih.gov/grants/funding/modular/modular.htm

This RFA will use the National Institutes of Health (NIH) R21 award mechanism. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. The program award provides one year of support. The award is not renewable, but institutions may request a second year without additional funds. This RFA is a one-time solicitation.

FUNDS AVAILABLE

A total budget for FY 2001 of approximately $1.2 million will be committed to fund applications submitted in response to this RFA. This funding level is dependent upon the receipt of a sufficient number of applications of high merit. The maximum annual direct cost per award will be

$150,000. It is anticipated that approximately 5 awards will be made in FY 2001. The anticipated award date is July 1, 2001.

OBJECTIVES

Background

As part of the Federal effort to eliminate racial and ethnic disparities in health, a need has been identified to expand the training of clinical researchers at Minority Institutions as one approach to fostering careers in clinical research addressing health disparities. Minority Institutions conduct high quality programs for educating ethnic minorities, and they represent a rich resource of talent with the appropriate cultural sensitivity and perspectives needed in clinical research. However, Minority Institutions have had difficulties developing and sustaining independent clinical research, and there is a paucity of ethnic minority clinical researchers who are pursuing successful clinical research careers.

Program

The ORMH, NCI, NCRR, NCCAM, NEI, NIA, NIAID, NIAMS, NIDCR, NIDDK, NIDA, and NINR have teamed to promote the first step in fostering the development of curricula in clinical research leading to a masters degree in Minority Institutions through this one year planning grant. This planning grant is seen as the first phase. The second phase, to be announced through a RFA in FY 2001, will be an award to assist in the actual development and implementation of the clinical research curriculum.

The planning grant will provide successful institutions funds to assess the resources, both at their home institution and potential affiliate institutions, for development of a curriculum for a Master of Clinical Research degree or Master of Public Health in a clinically relevant area. The curriculum is to focus on patient- or population-based research. For the purpose of this award, clinical research includes: patient-oriented research, epidemiologic and behavioral studies, and outcomes or health services research. The NIH defines patient-oriented research as research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) that requires direct interactions with human subjects. Patient-oriented research includes the development of new technologies, understanding mechanisms of human disease, therapeutic interventions and clinical trials.

The core curriculum is to include an array of clinical research-related topics of general interest such as biostatistics, bioethics, clinical trials design, observational study design, Federal policies and regulations that address research with human subjects (e.g., 45CFR46, FDA INDs, inclusion of women and minorities as well as children in clinical research projects), scientific writing for publication and competitive grants. Other topics may include human genetics, pharmacology, patenting and material transfer agreements, as well as legal and social issues. The scope of the core curriculum can be flexible to meet the perceived needs of the institution.

SPECIAL REQUIREMENTS

The narrative section (Research Plan) is restricted to 15 pages for this planning grant.

Critical elements of the Research Plan include the Program Director, the Curriculum Development Committee, the Institutional Environment, and the plan for developing a clinical research curriculum. The applicant must address the REVIEW CRITERIA listed in this RFA.

Program Director: The Program Director should possess the clinical research expertise, leadership and administrative capabilities required to lead the development of a clinical research curriculum.

Curriculum Development Committee: The Program Director must establish a Curriculum Development Committee that brings together key expertise for establishing the curriculum. This expertise should be documented by research accomplishments and/or teaching and mentoring records.

Institutional Environment: The Program Director should document the institutional environment for developing a clinical research curriculum. This includes current courses and programs which can be incorporated as well as the pool of potential participants (see ELIGIBILITY, above). Support of institutional officials should be documented. In addition, the Program Director is encouraged to bring in consultants from other institutions to provide input and/or critical review. Potential collaborations with other institutions may also be documented.

Plan: The Program Director should describe a plan for developing a clinical research curriculum, including use of existing resources, building partnerships with other institutions, use of consultants, and plans for critical review of the curriculum. The plan should include documentation of potential participants for the curriculum.

URLS IN NIH GRANT APPLICATIONS OR APPENDICES

All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Reviewers are cautioned that their anonymity may be compromised when they directly access an Internet site.

LETTER OF INTENT

Prospective applicants are asked to submit a letter of intent that includes a descriptive title of the proposed program, the name, address, telephone, FAX, and E-mail numbers of the Program Director, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted. Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows NIH staff to estimate the potential review workload and plan the review.

The letter of intent is to be sent to Dr. Julia B. Freeman, listed under INQUIRIES below, by October 23, 2000.

APPLICATION PROCEDURES

It is strongly recommended that prospective applicants contact the staff person listed under INQUIRIES early in the planning phase of the planning grant application. Such contact will help ensure that applications are responsive to the overall intent of this award.

The research grant application form PHS 398 (rev. 4/98) is to be used in applying for these grants. THE NARRATIVE PORTION (Research Plan) IS RESTRICTED TO 15 PAGES for this RFA. See SPECIAL REQUIREMENTS above.

Copies of application form PHS 398 are available at most institutional offices of sponsored research and from the Division of Extramural Outreach and Information Resources, National Institutes of Health, 6701 Rockledge Drive, MSC 7910, Bethesda, MD 20892-7910, telephone 301/435-0714, email: GrantsInfo@nih.gov; and on the internet at http://grants.nih.gov/grants/funding/phs398/phs398.html.

The modular grant concept establishes specific modules in which direct costs may be requested as well as a maximum level for requested budgets. Only limited budgetary information is required under this approach. The just-in-time concept allows applicants to submit certain information only when there is a possibility for an award. It is anticipated that these changes will reduce the administrative burden for the applicants, reviewers and Institute staff.

SPECIFIC INSTRUCTIONS FOR MODULAR GRANT APPLICATIONS

BUDGET INSTRUCTIONS

Direct costs may be requested in $25,000 modules, up to a total direct cost request of $150,000, ONLY ONE YEAR OF SUPPORT MAY BE REQUESTED. The total direct costs must be requested in accordance with the program guidelines and the modifications made to the standard PHS 398 application instructions described below:

PHS 398

o FACE PAGE: Items 7a and 7b should be completed, indicating Direct Costs (in $25,000 increments up to a maximum of $150,000) and Total Costs [Modular Total Direct plus Facilities and Administrative (F&A) costs] for the budget period Items 8a and 8b should be completed indicating the Direct and Total Costs for the proposed one year period of support.

o DETAILED BUDGET FOR THE INITIAL BUDGET PERIOD - Do not complete Form Page 4 of the PHS 398. It is not required and will not be accepted with the application.

o BUDGET FOR THE ENTIRE PROPOSED PERIOD OF SUPPORT - Do not complete the categorical budget table on Form Page 5 of the PHS 398. It is not required and will not be accepted with the application.

o NARRATIVE BUDGET JUSTIFICATION - Prepare a Modular Grant Budget Narrative page. (See http://grants.nih.gov/grants/funding/modular/modular.htm for sample pages.) At the top of the page, enter the total direct costs requested for one year. This is not a Form page.

o Under Personnel, list all project personnel, including their names, percent of effort, and roles on the project. No individual salary information should be provided. However, the applicant should use the NIH appropriation language salary cap and the NIH policy for graduate student compensation in developing the budget request.

For Consortium/Contractual costs, provide an estimate of total costs (direct plus facilities and administrative), each rounded to the nearest $1,000. List the individuals/organizations with whom consortium or contractual arrangements have been made, the percent effort of key personnel, and the role on the project. Indicate whether the collaborating institution is foreign or domestic. The total cost for a consortium/contractual arrangement is included in the overall requested modular direct cost amount. Include the Letter of Intent to establish a consortium.

Provide an additional narrative budget justification for any variation in the number of modules requested.

o BIOGRAPHICAL SKETCH - The Biographical Sketch provides information used by reviewers in the assessment of each individual's qualifications for a specific role in the proposed project, as well as to evaluate the overall qualifications of the research team. A biographical sketch is required for all key personnel, following the instructions below. No more than three pages may be used for each person. A sample biographical sketch may be viewed at: http://grants.nih.gov/grants/funding/modular/modular.htm

- Complete the educational block at the top of the form page;
- List position(s) and any honors;
- Provide information, including overall goals and responsibilities, on research projects ongoing or completed during the last three years.
- List selected peer-reviewed publications, with full citations;

o CHECKLIST - This page should be completed and submitted with the application. If the F&A rate agreement has been established, indicate the type of agreement and the date. All appropriate exclusions must be applied in the calculation of the F&A costs for the initial budget period and all future budget years.

o The applicant should provide the name and phone number of the individual to contact concerning fiscal and administrative issues if additional information is necessary following the initial review.

The RFA label available in the PHS 398 (rev. 4/98) application form must be affixed to the bottom of the face page of the application. Type the RFA number on the label. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2 of the face page of the application form and the YES box must be marked.

The sample RFA label available at:
http://grants.nih.gov/grants/funding/phs398/label-bk.pdf has been modified to allow for this change. Please note this is in pdf format.

Submit a signed, typewritten original of the application, including the Checklist, and three signed, photocopies, in one package to:

CENTER FOR SCIENTIFIC REVIEW (CSR)
NATIONAL INSTITUTES OF HEALTH
6701 ROCKLEDGE DRIVE, ROOM 1040, MSC 7710
BETHESDA, MD 20892-7710
BETHESDA, MD 20817 (for express/courier service)

At the time of submission, two additional copies of the application must be sent to:

Dr. Tommy L. Broadwater
Extramural Program Review Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Building 45, Room 5AS.25U
Bethesda, MD 20892-6500
Telephone: (301) 594-4952
FAX: (301)-402-2406
Email: broadwat@exchange.nih.gov

Applications must be received by the application receipt date of December 19, 2000. If an application is received after that date, it will be returned to the applicant without review.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by the Center for Scientific Review and responsiveness by Institute staff. Incomplete and/or non-responsive applications will be returned to the applicant without further consideration.

Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the NIAMS in accordance with the review criteria stated below. As part of the initial merit review, all applications will receive a written critique and may undergo a process in which only those applications deemed to have the

highest scientific merit, generally the top half of the applications under review, will be discussed, assigned a priority score, and receive a second level review by the National Arthritis and Musculoskeletal and Skin Diseases Advisory Council.

Review Criteria

The review criteria for the Planning Grant for Clinical Research Training in Minority institutions are:

- Clinical, scientific and administrative leadership qualifications and experience of the Program Director.

- Qualifications of the Curriculum Development Committee members, including the portfolio of on-going funded projects, publications and training experience in clinical research.

- Adequacy and availability of any necessary institutional facilities and resources.

- Adequacy of the plan for developing a clinical research curriculum, including use of existing resources, building partnerships with other institutions, use of consultants, and plans for critical review of the curriculum.

- Documentation of potential participants for the curriculum.

Schedule

Letter of Intent Receipt Date: October 23, 2000
Application Receipt Date: December 19, 2000
Peer Review Date: March/April 2001
Council Review: May/June 2001
Earliest Anticipated Start Date: July 1, 2001

AWARD CRITERIA

Award criteria that will be used to make award decisions include:

o scientific merit (as determined by peer review)
o availability of funds

o programmatic priorities.

INQUIRIES

Inquiries concerning this RFA are encouraged. NIAMS will be the lead in answering all inquiries. The opportunity to clarify any issues or answer questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

Dr. Julia B. Freeman
Director for Women's and Minority Health Issues, Extramural Program
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Building 45, Room 5AS.19F
Bethesda, MD 20892-6500
Telephone: (301) 594-5052
FAX: (301)-594-5052
Email: freemanb@exchange.nih.gov

Contacts for Institutes and Centers participating in this RFA:

Dr. Sanya A. Springfield
Chief, CMBB, OCTR, ODDES
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6116 Executive Blvd.
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Bethesda, MD 20892-8347
Telephone: (301) 496-7344
Fax: (301) 402-4551
Email: springfs@mail.nih.gov

Irene Grissom
Grants Management Specialist
National Center for Research Resources
6705 Rockledge Drive
Rockledge 1, Room 6212
Bethesda, MD 20892
Telephone: (301) 435-0848

Fax: (301) 480-3777
Email: grissomi@ncrr.nih.gov

Morgan N. Jackson, M.D., M.P.H.
Program Officer
National Center for Complementary and Alternative Medicine
National Institutes of Health
6707 Democracy Blvd., Room 106
Bethesda, MD 20892-5475
Telephone: 301-402-1278
Fax: 301-480-3621
Email: mj145m@nih.gov

Dr. Richard Mowery
Director, Collaborative Clinical Research
National Eye Institute
Executive Plaza South, Suite 350
6120 Executive Blvd., MSC 7164
Bethesda MD 20892-7164
Telephone: (301) 496-9110
Fax: (301) 402-0528
Email: rlm@nei.nih.gov

Dr. Sidney M. Stahl
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National Institute on Aging
Gateway Building, #533
7201 Wisconsin Ave.
Bethesda, MD 20892-9205
Telephone: (301) 402-4156
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Email: Sidney_Stahl@nih.gov

Dr. Norman Braveman
Assistant Director for Program Development
National Institute of Dental and Craniofacial Research
Natcher Building

45 Center Drive Room 4AN-24B
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Email: bravemann@de45.nidr.nih.gov

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National Institute of Diabetes and Digestive and Kidney Diseases
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Fax: (301) 480-4237
Email: agodoal@extra.niddk.nih.gov

Dr. Lula Beatty
Special Populations Office
National Institute of Drug Abuse
6001 Executive Blvd. MSC 9567
Bethesda, MD 20892-9567
Telephone: (301) 443-0441
Fax: (301) 480-8179
Email: lbeatty@ngmsmtp.nida.nih.gov

Dr. Janice Phillips
Program Director
National Institute of Nursing Research

Building 45, Room 3AN12A
Bethesda, MD 20892-6300
Telephone: (301) 594-6152
Fax: (301) 480-8260
Email: phillips@mail.nih.gov

Dr. Milton J. Hernandez
Director

Office of Special Populations and Research Training
National Institute of Allergy and Infectious Diseases
Room 2133
6700-B Rockledge Drive
Bethesda, MD 20892-7610
Tel: (301) 496-3775
FAX (301) 496-8729
mh35c@nih.gov

Direct inquiries regarding review issues to:

Dr. Tommy L. Broadwater
Chief, Review Branch, Extramural Program
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Building 45, Room 5AS.25U
Bethesda, MD 20892-6500
Telephone: (301) 594-4952
FAX: (301)-402-2406
Email: broadwat@exchange.nih.gov

Direct inquiries regarding fiscal matters to:

Melinda Nelson
Chief Grants Management Officer, Extramural Program
National Institute of Arthritis and Musculoskeletal and Skin Diseases
45 Center Drive, Room 5AS.49B
Bethesda, MD 20892-6500
Telephone: (301) 435-5278
FAX: (301)-480-5450
Email: nelsonm@exchange.nih.gov

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance Nos. 93.855 and 93.856. Awards are made under authorization of title III, Section 301 of the Public Health Service Act as amended. The Code of Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92 are

applicable to this program. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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